Group I: Claim 1, drawn polynucleotides and compositions containing same, classified in Class 536, subclass 23.1; Class 435, subclasses 243, 320.1, and 325; and Class 514, subclass 44.

Group II: Claim 2, drawn to methods of expression of polypeptides from polynucleotides, classified in Class 435, subclass 69.1.

Group III: Claims 3-9, drawn to a transformed plant, classified in class 800, subclass 278.

Upon the election of any of the foregoing groups, the Examiner has further required restriction to a single sequence as set forth in MPEP § 803.04.

In the telephonic interview of April 17, 2002, Applicant made a provisional election without traverse to prosecute the invention of Group 1 (claim 1) and SEQ ID NO: 1. Office Action at page 4; Interview Summary of April 17, 2002. As such, non-elected claims 2-9 have been cancelled without prejudice as being directed to a non-elected invention, and claim 1 has been amended to recite the elected SEQ ID NO: 1.

III. Specification Objections

In the Office Action at page 4, the Examiner has objected to the specification because "it contains an embedded hyperlink and/or other form of browser-executable code." Applicant has amended the specification to remove the phrase "http://" and embedded hyperlinks.

IV. Rejection under 35 U.S.C. § 101

Claim 1 was rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well established

utility as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). Applicant respectfully traverses this rejection.

The Examiner acknowledges that the specification describes the present invention may be "useful as markers, the isolation of polypeptides, hybridization probes, primers the isolation of full-length cDNAs or genes, which would be used to make protein and optionally further usage for mapping and numerous other generic genetic engineering usages, such as antisense production." Office Action at page 5. However, the Examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines because they are "non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acids being claimed." Office Action at page 6.

Applicant respectfully disagrees. It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes a utility, "a nucleic acid may be utilized to obtain a protein." Office Action at page 6.

This use and others stated in the specification and by the Examiner are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.* the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a

sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequence possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that the disclosed uses "are generic in nature and applicable to a myriad of such compounds." Office Action at page 6. In short, the Examiner's rejection, as it pertains to 35 U.S.C. § 101, rests on the premise that because other molecules might be used for the same purpose, the proposed utilities for the claimed molecules are legally insufficient. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicant notes that the claimed nucleic acid molecule encompasses many utilities. Furthermore, Applicant acquiesces that some of these utilities may be common

to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicant asserts that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Furthermore, utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they

must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

In support of the position that the claimed nucleic acid molecules lack substantial utility, the Examiner states that "one skilled in the art would have reason to doubt that proposed sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence." Office Action at page 7. The Examiner asserts that "[s]everal publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research." *Id.*

Applicant respectfully disagrees and refers the Examiner to the following articles, copies of which are enclosed for the Examiner's convenience, where sequence similarity is routinely used by those of ordinary skill in the art as a predictor of function. *See, e.g.,* Venter, *et al.*, The Sequence of the Human Genome, *Science*, *291*: 1304-1351 (2001); Woese, *et al.*, Conservation of Primary Structure in 16S rRNA, *Nature*, *254*: 83-85 (1975). Accordingly, Applicant maintains that one of ordinary skill in the art would have recognized, in light of Applicant's teachings, that at the time of filing Applicant had possession of the claimed invention for the uses described in the specification.

Furthermore, the utilities already described by the Examiner, *i.e.*, "useful as markers, the isolation of polypeptides, hybridization probes, primers the isolation of full-length cDNAs or genes", are not limited to a particular biological function. Office Action at page 5. It is well known in the art that hybridization conditions affect the

number of nucleic acid molecules isolated by any single nucleic acid probe. The limited pool of nucleic acid molecules or proteins recognized by SEQ ID NO: 1 are claimed based on sequence homology, not based on an admittedly unspecified biological function.

In view of the above, Applicant contends that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any relevant and credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection of claim 1, Under 35 U.S.C. § 112, First Paragraph, Enablement

In the Office Action, at page 8, the Examiner has rejected claim 1 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicant respectfully traverses this rejection and contend that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VI. Rejection of claim 1 Under 35 U.S.C. § 112, First Paragraph, Written Description

In the Office Action, at pages 8-10, the Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph, containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that

the inventor had possession of the claimed invention at the time of filing. This rejection is respectfully traversed for at least the reasons that follow.

An adequate written description of a genus of nucleic acids, such as recited in claim 1, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicant need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215,

211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicant to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner contends that the skilled artisan cannot envision the detailed chemical structure of the genus encompassed by the claim. Office Action at page 9. According to the Examiner's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Office Action at page 9-10. Applicant respectfully disagrees. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69 ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicant has provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable – they comprise a nucleic acid

molecule having the sequence selected from the group consisting of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claim 1 and SEQ ID NO: 1. Thus, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

VII. Rejection of claim 1 Under 35 U.S.C. § 102

Claim 1 stands rejected under 35 U.S.C. §102 as allegedly anticipated by Genbank accession numbers U28047, I65799, Z27167, and AA119201. Office Action at pages 10-11. The rejection is respectfully traversed.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985).

In the present application, claim 1 is directed to a nucleic acid molecule which encodes a cotton protein or fragment thereof comprising the nucleic acid sequence of SEQ ID NO: 1. The Examiner alleges that Genbank accession numbers U28047, I65799, Z27167, and AA119201 teach a "fragment" as set forth in the claim. Office Action at page 11. However, the Examiner has applied an untenable interpretation of claim 1 to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, fragments of

10 contiguous nucleotides, and thus concludes that the claim is anticipated by the cited reference. Office Action at page 11. A grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "cotton protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising", it is clear that it does not refer to a fragment of SEQ ID NO: 1.

As such, claim 1 is directed to a nucleic acid molecule which encodes a cotton protein or fragment thereof, *i.e.*, a fragment of a cotton protein, comprising the nucleic acid sequence of SEQ ID NO: 1. Whatever else Genbank accession numbers U28047, I65799, Z27167, and AA119201 teach, they do not disclose SEQ ID NO: 1 in its entirety. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 1, the reference cited by the Examiner does not anticipate pending claim 1. As such, withdrawal of this rejection is respectfully requested.

Conclusion

Applicant respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. As such, Applicant believes the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Applicant does not believe that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account Number 13-4125, referencing docket number 38-21(51770)B. Applicant likewise authorizes a charge to Deposit Account Number 13-4125 for any other fees related to the present application that are not otherwise provided for in the accompanying documents.

Respectfully submitted,

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Date: August 5, 2002

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Version with markings to show changes made

In the specification:

At page 4, lines 18 to 27:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) [(http://www.ddbj.nig.ac.jp/)] (www-ddbj.nig.ac.jp/); Genebank [(http://www.ncbi.nlm.nih.gov/Web/Genebank/Index.html)] (www-ncbi.nlm.nih.gov/Web/Genebank/Index.html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) [(http://www.ebi.ac.uk/ebi_docs/embl_db.html)] (www-ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequence[s] queries (BLASTN, BLASTX and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology*, *12*:76-80 (1994); Birren, *et al. Genome Analysis, 1*: 543-559 (1997)).

At page 22, lines 5 to 11:

A PCR probe is a nucleic acid molecule capable of initiating a polymerase activity while in a double-stranded structure with another nucleic acid. Various methods for determining the structure of PCR probes and PCR techniques exist in the art. Computer generated searches using programs such as Primer3 [(www-genome.wi.mit.edu/cgi-bin/primer/primer3.cgi)] (available on the World Wide Web at genome.wi.mit.edu/cgi-bin/primer/primer3.cgi), STSPipeline [(www-genome.wi.mit.edu/

cgi-bin/www-STS_Pipleine)] (available on the World Wide Web at genome.wi.mit.edu/cgi-bin/www-STS_Pipleine) or GeneUp (Pesole *et al., BioTechniques 25*:112-123 (1998) the entirety of which is herein incorporated by reference), for example, can be used to identify potential PCR primers.

In the claims:

1. (Once amended) A substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1[through SEQ ID NO: 4930].

10. (Added) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1.

11. (Added) A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1.